UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, et al. *ex rel.* Tricia Nowak & Enda Dodd Plaintiffs, v. MEDTRONIC, INC. Defendant.	Case Nos. 1:08-cv-10368 and 09-cv-11625 (DPW)

UNITED STATES OF AMERICA'S STATEMENT OF INTEREST ON DEFENDANT'S MOTION TO DISMISS

The United States, pursuant to 28 U.S.C. § 517, submits this Statement of Interest to respond to defendant's Motion to Dismiss. Although it has not intervened in this matter, the United States remains the real party in interest in this False Claims Act, 31 U.S.C. §§ 3729 *et seq.* ("FCA"), case and, given that the FCA represents a critical tool the United States uses to redress fraud on the government, an incorrect application of the FCA could harm the government's efforts to combat fraud in current and future cases. The United States submits this brief to address the following issues: (1) whether the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 355 & 357 ("FDCA"), precludes actions brought under the FCA; (2) the appropriate legal standards to evaluate the FCA's falsity, materiality, and causation prongs; and (3) the application of Federal Rule of Civil Procedure 9(b) in the context of FCA cases. Defendant also moves to dismiss the action under the public disclosure and first to file bars of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* ("FCA"). The government takes no position at this time on those arguments and submits that if the Court dismisses the matter on either of those grounds, it need

not reach defendant's other arguments or the issues addressed in the United States's brief. If the Court addresses the issues discussed herein, the United States respectfully urges the Court to reject the defendant's arguments for the reasons stated below. Also, the United States respectfully asks that if the Court dismisses the case, the dismissal be without prejudice to the United States.

I. THE FOOD, DRUG AND COSMETIC ACT DOES NOT PRE-EMPT OTHER FEDERAL LAWS.

Defendant argues that its allegedly false applications to the FDA for regulatory clearance of its stents cannot form the basis of an FCA claim because "[r]espondents cannot base an FCA claim on a theory that would require a jury to usurp the [FDA's] authority." Memorandum of Law in Support of Defendant's Motion to Dismiss Relators' Consolidated Complaint ("Defendant's Brief"), at 25. In support of this sweeping theory, defendant argues in favor of extending the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), to force the government to exercise only one remedy – under the FDCA– even though a company's conduct may violate numerous other federal laws. The argument is without merit; the reasoning in *Buckman* is inapplicable to FCA cases.

To start, the FCA grants the Attorney General the authority to investigate and file suits alleging the submission of false claims to the government. 31 U.S.C. § 3730(a). Only the Department of Justice, not the affected government agency, may compromise false or fraudulent claims on behalf of the government. 31 U.S.C. § 3711(b)(1). *See also Martin J. Simko Constr., Inc. v. United States*, 852 F.2d 540, 547 (Fed. Cir. 1988). Under defendant's reasoning, another government agency, the Food and Drug Administration ("FDA"), would first have to take some form of administrative action in order for the Department of Justice to proceed with an FCA

claim. This would effectively stifle law enforcement efforts and cede control over the assertion of FCA cases from the Department of Justice to other government agencies, contrary to prevailing law. *See United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 18 (1st Cir.), *cert. denied*, 546 U.S. 815 (2005) (recognizing the government's ability to elect remedy of its choice); *United States v. Sforza*, 326 F.3d 107, 113-14 (2d Cir. 2003) (proceeding under Federal Employees Compensation Act does not preclude recovery under FCA suit).

Moreover, the reasoning underlying the *Buckman* decision simply does not apply here. The Court in *Buckman* was concerned with the potential for state law, through allegations sounding in state tort law, to interfere with a federally created regulatory and enforcement scheme. The Court determined that a private plaintiff could not graft traditional state law theories of tort liability on top of a federal regulatory scheme intended to be enforced exclusively by the federal government. *See Buckman*, 531 U.S. at 352-53. This matter, in contrast, involves a claim under the federal FCA and is not a claim brought under the FDCA itself.[1] The FCA was enacted to redress unauthorized payments from the public fisc caused by fraud on the United States. This purpose compliments, rather than interferes with, the FDA's mandate to enforce its own regulations which, as the Supreme Court noted, it may do by: 1) seeking injunctive relief; 2) seeking civil penalties; 3) seizing products; and 4) pursuing criminal prosecutions. *See id*. at 349. The Court clearly embraced the idea of dual enforcability when it stated that the FDA's

[1] Defendant is also wrong in suggesting that relators' FCA suit represents an end-run around the FDA's regulatory authority. Relators brought this matter under the FCA. The FCA authorizes private individuals to bring suit on behalf of the government as a supplement to official law enforcement efforts. *See United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 224 n.5 (1st Cir.), *cert. denied*, 543 U.S. 820 (2004). The FCA therefore enables relators to bring actions even in instances where they suffered no injury as a result of a defendant's actions because under the statute they bring suit as a partial assignee of the United States. *See Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 773 (2000).

aforementioned remedies were "[i]n addition to the general criminal proscription on making false statements to the Federal Government."[2] *Id.* at 349.

Case law in this district has considered preemption in a similar context and rejected the position that FDCA violations pre-empt FCA liability. In *United States ex rel. Franklin v. Parke-Davis*, the Court noted that although not every regulatory violation creates a cause of action under the FCA, "the FCA *can* be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation made to obtain a government benefit." 147 F. Supp. 2d 39, 52 (D. Mass. 2001) (emphasis in original) (denying defendant's motion to dismiss). "Thus, the failure of Congress to provide a cause of action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government in violation of 31 U.S.C. § 3729(a)."[3] *Id.* at 53. The availability of regulatory and criminal sanctions under the FDCA therefore should not serve as a bar to recovery under the FCA.

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[2] Similarly, state FCA analogs compliment, rather than conflict with, the federal government's efforts to root out fraud and abuse. *See* Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 6031, 120 Stat. 7, 72 (Feb. 8, 2006) (providing for increased financial recoveries to states that enact statutes similar to the FCA).

[3] Other courts have similarly rejected arguments that regulatory remedies available to the government under existing regulatory regimes pre-empt the FCA. *See, e.g., United States ex rel. Fallon v. Accudyne Corp.*, 880 F. Supp. 636, 638 (W.D. Wis. 1995) (FCA remedies are distinct, and in addition to, statutory penalties available under Clean Water Act and Clean Air Act); *United States v. General Dynamics Corp.*, 19 F.3d 770, 777 (2d Cir. 1994) (Anti-Kickback Act "does not pre-empt remedies of the United States under the FCA").

II. LEGAL REQUIREMENTS OF AN FCA CLAIM.

A. Falsity Under the FCA.

1. The Alleged Conduct at Issue Can Cause the Submission of False Claims to Medicare.

In an effort to demonstrate that Medtronic's alleged conduct – *i.e.*, its alleged fraudulent statements to obtain clearance from the FDA through the 510(k) process rather than the more costly and time consuming Pre-Market Approval ("PMA") process and its alleged off-label promotion of biliary stents for use in the peripheral vasculature – did not cause the submission of false claims for reimbursement, the defendant argues that Medicare in fact provides coverage for the off-label use of medical devices. *See* Defendant's Brief, at 31-35. The problem with this argument is that it misses the point. Regardless of the regulatory status of a device *vis à vis* the FDA, coverage under Medicare is limited to medical services that are "reasonable and necessary" for the diagnosis or treatment of illness or injury. *See* 42 U.S.C. § 1395y(a)(1)(A) (defining scope of Medicare benefits). Although a physician may lawfully use a device off-label, there is no mandate that Medicare cover services involving such off-label uses. *See, e.g., Goodman v. Sullivan*, 891 F.2d 449 (2d Cir. 1989) ("Medicare statute does not require coverage for all medically necessary procedures . . . ."); *Svidler v. Dept. of Health and Human Servs.*, 2004 WL 2005781, at *5 (N.D. Cal. Sept. 8, 2004) ("Plaintiff then argues that because she is allowed to prescribe off label uses, Medicare must pay for off label uses. This leap of logic is unwarranted."). The statutory standard provides HHS "wide discretion to determine whether the numerous medical services and items covered by Medicare are 'reasonable and necessary' in particular circumstances . . . . [HHS] is not required to promulgate regulations or policies that, 'either by default rule or by specification, address every conceivable question' that may arise."

Willowood of Great Barrington, Inc. v. Sebelius, 638 F. Supp. 2d 98, 105 (D. Mass. 2009). *See also Diapulse Corp. of Am. v. Sebelius*, No. 1:06-CV-2226, 2010 U.S. Dist. LEXIS 25003 , at *32-33 (E.D.N.Y. Jan. 21, 2010) (Court agreed with HHS that "a device must receive FDA approval or clearance . . . to be eligible for Medicare coverage, but FDA approval/clearance alone does not entitle that device to coverage."). When a medical device is cleared or approved for a particular intended use, federal healthcare programs still may deny coverage for procedures involving that medical device, including one or more off-label uses of the device.[4] *See Svidler*, 2004 WL 2005781 (holding that medical procedure involving the use of an FDA-cleared medical device for an off-label use was experimental and not covered under Medicare). To the extent that a healthcare provider seeks reimbursement for a procedure that is ineligible for payment under a federal healthcare program, either because the program bars coverage for a particular off-label use of a device or because the program places other conditions on coverage that are not satisfied, the claim is false.

In this instance, Medicare issued a National Coverage Determination ("NCD") that neither explicitly permitted nor excluded coverage for the off-label use of defendant's devices in the peripheral vasculature. *See National Coverage Determination for Percutaneous Transluminal Angioplasty (PTA) (20.7)* (attached as Exhibit B to the Nemirow Decl.). Instead, CMS deferred to the judgment of local contractors, who, at their discretion, announce coverage decisions through local coverage determinations ("LCDs"). Local Medicare contractors therefore could choose to issue guidance to set forth the conditions under which they would reimburse providers for the off-label use of defendant's devices in peripheral vascular

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[4] The Ault Memo (attached as Exhibit A to the Nemirow Decl.) cited by defendant as dispositive has been superceded by subsequently enacted regulations. *See* 60 Fed. Reg. 48417, 48423 (Sept. 19, 1995); *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 75 (2nd Cir. 2006).

procedures. *See* Medicare Program Integrity Manual, Ch. 13, §§ 13.1.3 and 13.4 (available at http://www.cms.gov/manuals/downloads/pim83c13.pdf

In some instances, local Medicare contractors issued guidance that limited reimbursement to instances where an FDA approved stent is used for the FDA approved indication or an FDA approved stent is used in a different part of the peripheral vasculature and its use is supported by peer medical literature. *See, e.g.*, Trailblazer Health Enterprises, LLC, *Non-Coronary Vascular Stents* (4S-156AB) ("Stent placement is covered by Medicare only when an FDA-approved stent is: Used for the FDA-approved indications; Or, Used for the above indications supported by the peer medical literature");[5] Wisconsin Physicians Service Insurance Corp., *Non-Coronary Vascular Stents* (CV-528) (same).[6] To the extent that an LCD provides that coverage is afforded only for procedures using devices that specifically have been approved by FDA or have support in peer-reviewed medical literature for use in the vascular system, other procedures utilizing devices that fall outside the parameters established by the LCD may not be covered. As a final matter, Medicare coverage of these devices and their specific off-label use is a factual issue that is not subject to determination at the motion to dismiss stage.

In addition, in certain circumstances, a claim also may be rendered false under the FCA if a party engages in a fraudulent course of conduct. Thus, courts have had no difficulty concluding that when a defendant engaged in underlying criminal conduct (such as bid rigging or

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[5] Available at http://www.cms.gov/mcd/viewlcd.asp?lcd_id=28638&lcd_version=4&basket=lcd%3A28638%3A4%3A%3Cb%3E+Non%2DCoronary+Vascular+Stents+%E2%80%93+4S%2D156AB%3C%2Fb%3E%3AMAC+%2D+Part+B%3ATrailBlazer+Health+Enterprises%7C%7C+LLC+%28402%29%3A.

[6] Available at: http://www.cms.gov/mcd/viewlcd.asp?lcd_id=26634&lcd_version=11&show=all.

the payment of a kickback) or violated a regulation or made a false statement to procure a government benefit, the subsequent claims are false. *See, e.g., United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543 (1943) (holding that, where government contract secured by fraudulent bid rigging, "[the] fraud did not spend itself with the execution of the contract[;] [i]ts taint entered into every swollen estimate which was the basic cause for payment of every dollar paid"); *Scolnick v. United States*, 331 F.2d 598 (1st Cir. 1964) (imposing FCA liability based on mere cashing of check to which payee was not entitled); *Murray & Sorenson v. United States*, 207 F.2d 119, 123 (1st Cir. 1953) (secret tip that contractor could raise his bid on behalf of the corporate defendant to a price higher than would otherwise have been submitted constituted fraud); *United States v. Dynamics Research Corp.*, 2008 WL 886035, *10 (D. Mass. Mar. 31, 2008) ("[W]here a claim for payment is the result of a fraudulent process - bid rigging, self-dealing, etc. - such that the reliability and trustworthiness of a claim is compromised, the claim may be considered false under the FCA despite its facial accuracy."); *United States ex rel. Longhi v. Lithium Power Technologies Inc.*, 575 F.3d 458, 471-73 (5th Cir. 2009), *cert. denied*, ___ U.S. ___, 130 S.Ct. 2092 (2010) (where government fraudulently induced to award grant by material false statements on grant application, every invoice submitted for grant was false claim and Government's damages was entire amount paid out on grant); *United States v. Incorporated Village of Island Park*, 888 F. Supp. 419, 439 (E.D.N.Y. 1995) ("[T]he [FCA] is violated not only by a person who makes a false statement or a false record to get the government to pay a claim, but also by one who engages in a fraudulent course of conduct that causes the government to pay a claim for money.")

2. Rules Governing Other Federal Programs Preclude Coverage.

In addition to the Medicare program, other federal health care programs, such as those administered by the Veteran's Administration and the Department of Defense, have their own rules to determine whether program payment will be made for off-label use of medical devices. Defendant's Brief dismissively suggests that the end result of the analysis under these programs' rules would be similar to Medicare. *See* Defendant's Brief, at 5 n.2. Its argument is incorrect.

For example, the federal military healthcare plan known as TRICARE categorically excludes coverage for "[u]nproven drugs, devices, and medical treatments or procedures." 32 C.F.R. § 199.4(g)(15). TRICARE defines "unproven" as lacking necessary FDA approval, clearance, or an investigational device exemption. 32 C.F.R. § 199.4(g)(15)(i)(A)-(B). According to its provider manual, "[i]f the device is used for a non-covered or excluded indication, benefits may not be allowed." TRICARE Manual Chap. 8 § 5.1(II)(B).[7] Thus, TRICARE will not reimburse health care providers for a procedure utilizing an unproven device, and claims utilizing a non-covered device are therefore false. To the extent a third party caused the submission of the false claim, liability under the FCA may accrue.

3. The FCA Does Not Require Proof of a "Double Falsehood."

The defendant asserts that a device manufacturer's promotion of a device for an off-label indication cannot support an FCA claim unless the manufacturer made fraudulent misrepresentations to a federal healthcare provider. *See* Defendant's Brief, at 39. Thus, the defendant argues that the FCA requires proof that a defendant made or caused both false statements and a false claim. However, the argument conflates the first two sections of the FCA, which provide independent and distinct bases for FCA liability. *Compare* 31 U.S.C. § 3729(a)(1) *with* (a)(2). Liability under Section 3729(a)(1) does not require proof that a

[7] Available at: http://www.tricare.mil/tp02/C8S5_1.PDF.

defendant made a false statement; it requires only proof that the defendant presented or caused the presentment of a false claim. *See Parke-Davis*, 2003 WL 22048255, at *1 ("While § 3729(a)(2) contains a double-falsehood requirement . . ., there is no double falsehood requirement under § 3729(a)(1): One will suffice."); *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731-33 (1st Cir. 2007) (separately analyzing false statement allegations under Section 3729(a)(2)).

Moreover, with respect to Section 3729(a)(2),[8] the defendant contends that the false statement requirement cannot be satisfied by showing that a defendant promoted a device for an off-label use. *See* Defendant's Brief, at 39. As courts have long held both in the FCA context and otherwise, for a statement to be "false," it need not be an affirmative misrepresentation; a material omission will suffice: "[H]alf the truth may obviously amount to a lie, if it is understood to be the whole." *W. Page Keeton, Prosser & Keeton on the Law of Torts* § 106, at 738 (5th ed. 1984). *See also United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 43 (D. Mass. 2000) (an "omitted material fact," such as the existence of illegal kickbacks, may be actionable under the FCA)*; Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732 (7th Cir. 1999) (observing that a half-truth may amount to a false statement under the FCA in certain circumstances); *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d

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[8] Section 4(f)(1) of the Fraud Enforcement Recovery Act ("FERA") amended section 3729(a)(2) and recodified it as section 3729(a)(1)(B) of the FCA. *See* Pub. L. No. 111-21, § 4, 123 Stat. 1617,1621 (2009) FERA made this change retroactive to all cases pending as of June 7, 2008, regardless of when the conduct took place. *See United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 855 n.* (7th Cir. 2009) (noting FERA's application to conduct after May 20, 2009 except for the changes to section 3729(a)(1)(B)); *United States ex rel. Carter v. Halliburton Co.*, No. 1:08cv1162 (JCC), 2009 WL 2240331, at *5 n.3 (E.D. Va. July 23, 2009) ("Because this case was pending on June 7, 2008, the Court has applied the amendment in § 3729(a)(1)(B) (2009) to Count 4, a claim originally brought under § 3729(a)(2) (1994)"). Thus, to the extent the defendant suggests that the old section 3729(a)(2) applies here, it is wrong. *See* Defendant's Brief, at 8 n.8.

196, 199 (D.C. Cir. 1995) (finding that false progress reports may constitute false statements under the FCA); *United States ex rel. Fry v. Guidant Corp.*, 2006 WL 2633740, at *10-11 (M.D. Tenn. Sept. 3, 2006) (finding representation was rendered false by concealment of material information). Thus, a statement encouraging a doctor to use a device for an off-label use could well amount to a half truth and satisfy the false statement requirement of section (a)(2), where, for example, the sales representative fails to mention that the evidence does not support the device's efficacy for the use he or she is promoting, the FDA has specifically concluded that the device is not effective for that use, or there are significant, undisclosed side effects that make the device not safe for that use.

B. Medicare's Prospective Payment System Does Not Preclude Claims For Non-Covered Devices Under The FCA.

In an effort to demonstrate that its alleged off-label marketing scheme was not material to the government's payment decisions, the defendant argues that the government's payment system is such that the claims for payment would be reimbursed nonetheless. *See* Defendant's Brief, at 35-36. In essence, the defendant is arguing that no false claims may result, ever, simply because CMS has made the decision to pay claims at a bundled rate. That is incorrect.

For example, courts have held that unallowable charges, even when encompassed by a fixed rate under CMS's prospective payment system, render a claim false. In *United States ex rel. Morris v. Crist*, No. C-2-97-1395, 2000 WL 432781, at *1 (S.D. Ohio Mar. 29, 2000), the relator alleged that the defendant submitted false claims to the government by failing to identify unallowable research costs on its Medicare claims for payment. The court found that "the entire bill represents a claim against the United States to be paid or approved, regardless of whether or not the payment is for a flat fee." *Id.* at *5. Therefore, even though the government's

reimbursement amount, which was prospectively determined by Medicare, was not affected by the inclusion of unallowable research charges, the inclusion of unallowable charges could render the entire claim false. *See id.* at *6. *Cf. United States ex rel. Hutcheson v. Blackstone Med., Inc.*, No. 06-11771-WGY, 2010 WL 938361, at *16 (D. Mass. Mar. 12, 2010) (false certification may be material to government's payment decision under prospective payment system). The mechanics of reimbursement, therefore, cannot be used to insulate a defendant from liability.[9]

C. Liability Under The FCA Is Appropriate When A Party Causes The Submission Of A False Claim.

Defendant's argument that it did not cause the submission of false claims because it was not involved in the claims process and did not have the purpose of getting the United States to pay false claims (Defendant's Brief, at 34-35) does not reflect the standard for demonstrating causation under the FCA. The FCA expressly imposes liability on individuals who knowingly cause someone else to submit a false claim for payment. 32 U.S.C. § 3729(a)(1). In interpreting the statute, courts have imposed FCA liability on defendants who caused others to submit false claims for payment, even if the party submitting the claim was unaware of its falsity. *See, e.g., United States v. Bornstein*, 423 U.S. 303 (1976) (imposing liability on subcontractor whose

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[8] Defendant's argument that the decision whether or not to use a device has no effect on Medicare payment similarly fails. With respect to peripheral vascular procedures, procedures consisting of an angioplasty with implantation of a stent are reimbursed at a higher rate than procedures involving angioplasty alone. For example, the Medicare Ambulatory Payment Classification ("APC") system used for reimbursing hospital outpatient peripheral vascular stenting procedures in 2007 set the national reimbursement amount for APC 0229, transcatheter placement of intravascular stent, at $4,208.70. *See 2007 Hospital Outpatient PPS Addendum A and Addendum B Updates, available at* http://www.cms.gov/HospitalOutpatientPPS/AU/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1190929&intNumPerPage=10. In contrast, the same procedure without insertion of an intravascular stent is classified as APC 0081, Non-Coronary Angioplasty or Atherectomy, and is reimbursed in the amount of $2,639.19. *See id.*

faulty electron tubes were incorporated into radio kits sold to United States); *United States v. Rivera*, 55 F.3d 703, 707 (1st Cir. 1995) (imposing liability on defendant who knowingly caused third party to unwittingly submit false claims).

In cases alleging off-label marketing of a medical device, it is reasonably foreseeable that employing an army of sales representatives to promote the device for conditions that largely affect the elderly population will lead to physicians ultimately prescribing and implanting the device and seeking reimbursement from Medicare, among other payors. *See, e.g., United States ex rel. Franklin v. Parke-Davis*, No. Civ.A. 96-11651 PBS, 2003 WL 22048255, at *2 (D. Mass., Aug. 22, 2003) (foreseeable that non-fraudulent off-label promotion of pharmaceutical product would result in false Medicaid claims). *See also Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008) (noting that a defendant is responsible for the "natural, ordinary and reasonable consequences of his conduct"). Thus, a defendant that fraudulently introduces a product to market and then uses its sales force to promote the off-label use of the product may be found to have knowingly caused health care providers to submit false claims for reimbursement.

III. FCA COMPLAINTS NEED NOT IDENTIFY SPECIFIC INDIVIDUAL FALSE CLAIMS FOR PAYMENT.

As a general matter, a viable FCA complaint need not identify specific false claims. While it is clear that Federal Rule of Civil Procedure 9(b) applies to complaints alleging violations of the FCA, the rule only requires that an FCA complaint be sufficiently detailed to put a defendant on notice of the allegations against it. *See United States ex rel. Duxbury v. Ortho Biotech Products*, 579 F.3d 13, 29 (1st Cir. 2009), *cert. denied*, ___ U.S. ___, 2010 WL 2471083 (2010); *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 (1st Cir. 2007). *See also, e.g., United States ex rel. Lusby v. Rolls Royce Corp.*, 570 F.3d 849, 854 (7th Cir.

2009) ("[w]e don't think it essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit"); *United States ex rel. Grubbs v. Kanneganti et al.*, 565 F.3d 180, 190 (5th Cir. 2009) ("the 'time, place, contents and identity' standard is not a straightjacket for Rule 9(b)"). In instances such as this one, where an FCA complaint alleges that a defendant caused false claims to be presented by a third party (i.e., through hospitals or other medical providers), the complaint may satisfy the requirements of Rule 9(b) by including allegations of a scheme to cause the submission of false claims along with factual or statistical information sufficient to support an inference that false claims for payment were likely submitted to the government. *See United States ex rel. Duxbury*, 579 F.3d at 29.

In *Duxbury*, for example, the First Circuit held that the relator satisfied the requirements of Rule 9(b) even though he did not identify a single false claim submitted to the government. *See id.* at 29-30. The court held that by making allegations that the defendant paid kickbacks to specific providers and that the providers were reimbursed by Medicare, without actually referencing specific claims for payment or reimbursement received, the relator sufficiently alleged the "who, what, where, and when" of the allegedly false representation. *See id.* at 30. Other decisions from this Court and throughout the country have reached similar conclusions. *See, e.g., In re Pharmaceutical Industry Average Wholesale Price Litigation*, 538 F. Supp. 2d 367, 391 (D. Mass. 2008) (applying *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720 (1st Cir. 2007) and denying motion to dismiss kickback claims under Rule 9(b) because relator's allegations were sufficient to permit inference that false claims were submitted); *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d at 49 ("Although the relator here does not have specific prescriptions for Medicaid patients for off-label uses made by doctors in reliance on the fraudulent representations, Franklin (unlike the relator in *Eastman Kodak*) does not reasonably

have pre-discovery access to that patient specific information."); *United States ex rel. Walker v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005), *cert. denied sub nom., R & F Properties of Lake County, Inc. v. Walker*, 549 U.S. 1027 (2006) (declining to dismiss FCA case under Rule 9(b) where relator set forth basis for allegation that defendants submitted false claims).

The United States takes no position at this time on whether the relators' complaint in this case is pleaded with sufficient particularity to support the inference that false claims were submitted to the government, or that relators have adequately alleged that the defendant engaged in conduct that caused false claims to be submitted. Nor does the United States take a position as to whether the complaint complies with Rule 9(b) with respect to other issues. The United States merely submits that the complaint should not be dismissed based on the defendant's argument that it is deficient for failing to list individual claims for payment. *See* Defendant's Brief, at 37-39.

CONCLUSION

For the foregoing reasons, the United States respectfully asks the Court to reject the defendant's arguments addressed in this statement of interest. The United States takes no position at this time on defendant's other legal arguments.

Respectfully submitted,

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July 2, 2010

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